UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JILL A. WHITCOMB,

Plaintiff,

v.

SYLVIA BURWELL,
Secretary of Health and Human Services,

Defendant.

Case No. 13-C-990

William E. Duffin
United States Magistrate Judge

DEFENDANT'S RESPONSE TO PLAINTIFF'S MOTION FOR ATTORNEY FEES UNDER THE EQUAL ACCESS TO JUSTICE ACT

I. INTRODUCTION

This Court should deny Plaintiff's motion for attorney's fees totaling $26,741.34 under the Equal Access to Justice Act (EAJA) because the Secretary's decision to litigate this case was substantially justified. The Court agreed with the Secretary that neither National Coverage Determination (NCD) 40.2 nor Local Coverage Determination (LCD) L27231 provide Medicare coverage for cover continuous glucose monitors (CGMs). However, the Court disagreed with the Secretary's final decision denying coverage for a CGM based on Policy Article A47238, which specifically excludes coverage for CGMs because they are precautionary devices not covered under Medicare's durable medical equipment (DME) benefit. Although the Court disagreed with the Secretary's reliance on Policy Article A47238, the evidence in the record shows that the Secretary acted reasonably when relying on the policy article to support her final decision. Consequently, Plaintiff is not entitled to a fee award under EAJA.

II. BACKGROUND

The underlying dispute in this case stems from Plaintiff's request that her Medicare Advantage (MA) organization, UnitedHealthcare/SecureHorizons (SecureHorizons), provide coverage for the long-term use of a CGM. Under the MA program, 42 U.S.C. § 1395w-21 *et seq.*, MA organizations are required to offer, at a minimum, the same benefits offered by Medicare Parts A and B. 42 U.S.C. § 1395w-22(a)(1); 42 C.F.R. § 422.100(c)(1). Additionally, MA organizations are required to comply with NCDs, general coverage guidelines included in Medicare manuals and instructions, and written coverage decisions of Medicare Administrative Contractors (MACs) with jurisdiction for claims in the geographic area in which services are covered under a MA plan. 42 C.F.R. § 422.101. Thus, SecureHorizons' coverage for CGMs is governed by traditional Medicare's coverage rules, applicable NCDs and LCDs, and any guidelines contained in Medicare's manuals and instructions.

SecureHorizons initially denied Plaintiff's request for a CGM based on Policy Article A47238, which states that CGMs are precautionary devices not covered under Medicare's DME benefit. A.R. 266. SecureHorizons' denial was consistent with its Diabetic Management, Equipment and Supplies Policy. A.R. 570-578. Under this policy, SecureHorizons noted that CGMs are intended to supplement, not replace, standard self-monitoring of blood glucose levels performed with a fingerstick. A.R. 577. Moreover, SecureHorizons' policy emphasized that a CGM should only be worn for a maximum of three days because the purpose of a CGM was to obtain values over a short period of time so that a treating practitioner could adjust an individual's treatment plan depending on the data collected by the CGM. *Id.* In other words, as stated in SecureHorizons' policy, "*Long term use or frequent use of continuous glucose monitoring will be* ***denied as not medically necessary.***" *Id.* (emphasis in original). Additionally,

SecureHorizons' policy noted that all DME MACs issued policy articles stating that CGMs are not covered under Medicare's DME benefit because they are precautionary devices. A.R. 573-574.

SecureHorizons' denial was upheld by Maximus Federal Services, the independent review entity charged with reviewing unfavorable decisions issued by MA organizations. A.R. 259-260. In response, Plaintiff filed an appeal before an administrative law judge (ALJ). The ALJ reversed SecureHorizons' decision denying coverage. A.R. 79-89. Despite acknowledging that Policy Article A47238 specifically excluded CGMs from coverage, the ALJ ordered SecureHorizons to cover the requested CGM based on Plaintiff's medical condition and because he found that neither NCD 40.2 nor LCD L27231distinguished between coverage for CGMs and traditional metered glucose monitors. A.R. 87-89.

SecureHorizons challenged the ALJ's decision by requesting that it be reviewed by the Medicare Appeals Council (the Council). The Council reversed the ALJ's decision. A.R. 23-29. In doing so, the Council explained that the ALJ's finding that Plaintiff satisfied the requirements outlined in NCD 40.2 and LCD L27231 was erroneous because neither of these coverage determinations provided coverage for CGMs. Rather, the Council found that the language included in NCD 40.2 and LCD L27231 only provided coverage for glucose monitors that obtain readings through fingersticks using lancets and reagent strips. A.R. 27. Further, the Council noted that LCD L27231's related policy article (Policy Article A47238) unambiguously denied coverage for the requested CGM because it was a precautionary device not covered under Medicare's DME benefit. *Id.* Thus, the Council held that the ALJ incorrectly found that the record provided sufficient information that supported his departure from the coverage standards outlined by Medicare and its contractor. *Id.*

The Council also explained that while Medicare coverage was not available for the requested CGM, this did not leave Plaintiff without means to test her glucose levels as often as her physician ordered. A.R. 28. Citing to LCD L27231, the Council advised Plaintiff that Medicare covered as many supplies for non-continuous blood sugar testing as she needed, provided her physician documented her need for supplies greater than the typical utilization standards. A.R. 27-28.

The Council emphasized that when the preceding Local Medical Review Policy (LMRP) was converted to LCD L27231 and Policy Article A47238, LCD L27231 did not make a coverage determination regarding CGMs. A.R. 28. Plaintiff understood this and argued that Medicare needed to revisit its policies relating to CGMs. *Id.* However, as the Council stated, the claims appeal process was not the appropriate forum for a challenge to a coverage policy. Rather, the Council advised Plaintiff that if she wanted to challenge the validity of LCD L27231 she needed to follow the procedures under 42 C.F.R. Part 426. *Id.*

Following the Council's decision, Plaintiff requested that the Council reconsider its decision. Although the Council declined to reopen its decision, it did address Plaintiff's concerns regarding its previous decision. A.R. 5-9. In response to Plaintiff's argument that the requested CGM should be covered because it was useful in helping her control her glucose levels, the Council reiterated that in order for coverage to be available for DME, the DME had to meet all of the conditions for coverage outlined in the Medicare statute, regulations, and guidelines. Thus, the Council advised Plaintiff that whether the CGM was useful did not necessarily mean that Medicare would provide coverage for it. Additionally, while the Council agreed with Plaintiff that the term "precautionary" was not defined in the Medicare statute or regulations, it found that the term was likely used by the Medicare contractor in Policy Article

A47238 to distinguish CGMs from devices that are medically necessary. A.R. 7. Finally, the Council reminded Plaintiff that if she wished to challenge the validity of LCD L27231, she needed to advance her arguments using the procedures under 42 C.F.R. Part 426. A.R. 8.

Plaintiff challenged the Secretary's final decision in a suit filed before this Court. The Court agreed with the Secretary that neither NCD 40.2 nor LCD L27231 provide coverage for CGMs. Decision and Order, p. 7 (Document 51). The Court, though, found that the Secretary erred in relying on Policy Article A47238 to deny coverage. *Id.* According to Decision and Order, allowing the Secretary to rely on a policy article to deny coverage undermines Section 522 of BIPA because Section 522 allows for challenges of LCDs, not policy articles. Thus, the Court reasoned that allowing the Secretary to rely on Policy Article A47238 would open the door to a system whereby coverage denials are based on policies that may not be challenged. Consequently, the Court found that Policy Article A47238 is not entitled to substantial deference under 42 C.F.R. § 405.1062(a). *Id.* at 9. Having decided that the Secretary erred in relying on Policy Article A47238, the Court remanded the case to the Secretary to assess whether the requested CGM is reasonable and necessary and not otherwise excluded from coverage.

III. ARGUMENT

A. The Equal Access to Justice Act

The EAJA is not an automatic fee shifting statute. *See Federal Election Comm'n v. Rose*, 806 F.2d 1081, 1087 (D.C. Cir. 1986); *Commissioner, I.N.S. v. Jean,* 496 U.S. 154, 155 (1990). The EAJA provides for an award of attorney fees and other expenses to a party who prevails in litigation against the United States if: (1) he was a "prevailing party"; (2) the government's position was not "substantially justified"; (3) there exist no special circumstances that would make an award unjust; and (4) he filed a timely application. 28 U.S.C. §§ 2412(d)(1)(A),(B).

In the present case, Plaintiff is a prevailing party because the magistrate judge remanded the case to the Secretary pursuant to Sentence 4 of 42 U.S.C. § 405(g). *Shalala v. Schaefer,* 509 U.S. 292, 301-302 (1993). Additionally, no special circumstances would make an award unjust and the application for fees was timely filed. 28 U.S.C. § 2412(d)(1)(A). Thus, the only issue before the Court is whether the Secretary's position was substantially justified. *Id.*

The Secretary bears the burden of showing that her position was substantially justified. *Marcus v. Shalala,* 17 F.3d 1033, 1036 (7th Cir. 1994). Although the phrase "substantially justified" is not defined in the EAJA, the Supreme Court has explained that the government's position is substantially justified if it is "'justified in substance or in the main'—that is, justified to a degree that could satisfy a reasonable person." *Pierce v. Underwood*, 487 U.S. 552, 565 (1988). In offering further guidance regarding the substantially justified standard, the Supreme Court stated:

> [A] position can be substantially justified even though it is not correct, and we believe that it can be substantially (i.e., for the most part) justified if a reasonable person could think it correct, that is, if it has a reasonable basis in law and fact.

Id. at 566 n. 2. Thus, substantially justified does not mean "justified to a high degree," but rather is satisfied if there is a "genuine dispute" or if reasonable people could differ as to the appropriateness of the contested action. *Stein v. Sullivan,* 966 F.2d 317, 320 (7th Cir. 1992) (citing *Underwood*, 487 U.S. at 565).

Moreover, a loss on the merits does not equate with a lack of substantial justification. *See Underwood,* 487 U.S. at 569 ("[O]bviously, the fact that one agreed or disagreed with the Government does not establish whether its position was substantially justified. Conceivably, the agency could take a position that is not substantially justified, yet win; *even more likely, it could take a position that is substantially justified, yet lose.*") (emphasis added). Therefore, a court's

statement in its merits decision that the government did not have a rational ground for its decision does not imply a lack of substantial justification for the agency's position. *Kolman v. Shalala*, 39 F.3d 173, 177 (7th Cir. 1994).

Significantly, the substantial justification standard is distinct from the substantial evidence standard, which governs review of the Secretary's final decision. *Cummings*, 950 F.2d at 498. As *Cummings* observed, these two standards of review "are used at different stages and involve different tests." *Id.* At the EAJA stage, the court must take a fresh look at the case from the EAJA perspective and reach a judgment independent from the ultimate merits decision. *Rose*, 806 F.2d at 1087-90. In other words, at the EAJA stage, the test is "whether the agency had a rational ground for thinking it had a rational ground for its action." *Kolman*, 39 F.3d at 177. As such, this Court should deny the application for EAJA fees as long as the Secretary reasonably argued this case. *See Underwood*, 487 U.S. at 565; *Stein*, 966 F.2d at 320.

B. The Secretary's Position Was Substantially Justified

When considering whether to award attorney fees under EAJA, the court determines whether the government's position during the administrative and litigation phases were substantially justified. 28 U.S.C. § 2412(d)(2)(D); *Cummings*, 950 F.2d at 496. However, the court need only make one determination as to whether the government's position as a whole was substantially justified during the entire civil action. *Commissioner, I.N.S. v. Jean*, 496 U.S. 154, 159 (1990).

The Secretary's position throughout the administrative proceedings and the litigation before this Court has been substantially justified. The administrative review process under the MA program includes five levels of review before a beneficiary may seek judicial review of the Secretary's final decision. 42 U.S.C. §1395w-22(g). Here, Plaintiff's request for a CGM was denied during four of the five levels of administrative review. These coverage denials were

reasonably based on Medicare coverage rules. For items and services to be covered under Medicare, they have to be eligible for coverage under a defined Medicare benefit category, be reasonable and necessary for the diagnosis or treatment of an injury or illness, and meet all applicable statutory and regulatory requirements. Apart from the ALJ, each reviewing body found that there was no coverage for the CGM based on the language in Policy Article A47238, which states that CGMs are not covered under Medicare's DME benefit because they are precautionary devices. In other words, the Secretary's final decision, and the decisions preceding it, found that the CGM was not covered because it did not fit within a Medicare benefit category. As noted in the Medicare Benefit Policy Manual, Chapter 15, Section 110.1.B.2, precautionary-type devices are considered presumptively non-medical and therefore not covered under Medicare's DME benefit.[1] Consequently, the Secretary's final decision was reasonably based on Medicare coverage guidelines. Thus, it was reasonable for the Secretary to defend her final decision in the litigation before this Court.

Plaintiff urges this Court to find that the Secretary acted unreasonably based on the fact that the ALJ held in her favor. The fact that Plaintiff prevailed at one of the five levels of review does not entitle her to an award under EAJA. As noted above, the Court must determine whether the Secretary's position throughout the entire civil action was reasonable when deciding to grant an award under the EAJA. As discussed above, the Secretary's position was reasonably based on Medicare coverage guidelines set forth in Policy Article A47238 and the general guidelines for DME. Moreover, contrary to Plaintiff's assertion, she did not prevail convincingly before the ALJ. The ALJ's decision in favor of Plaintiff was largely based on his finding that CGMs are covered by Medicare because NCD 40.2 and LCD L27231 do not distinguish between non-

[1] Medicare's Benefit Policy Manual, Internet Only Manual 100-2, can be found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html.

continuous glucose monitors and CGMs. This finding, though, was rejected by the Council and this Court. Indeed, both the Council and this Court found that NCD 40.2 and LCD L27231 only provide coverage for non-continuous blood glucose monitoring performed by a fingerstick using a lancet and reagent strips. Thus, Plaintiff's assertion that the ALJ's finding in her favor shows that the Secretary's position was unreasonable lacks merit because the ALJ's primary finding was ultimately reversed by the Council and affirmed by this Court.

Plaintiff also attempts to show that the Secretary's position in this case was unreasonable by referencing two ALJ decisions that found in favor of beneficiaries whose requests for CGMs were denied. Plaintiff's reliance on other administrative proceedings is unavailing. First, the regulations specifically state that ALJ decisions that do not adhere to policy guidance, such as manual instructions and program memorandum, are not precedential. 42 C.F.R. § 406.1062(b). Second, the cases Plaintiff relies upon are distinguishable from the present case. Based on the decisions Plaintiff submitted, it appears that in those cases the MA organization and the contractor did not present evidence supporting the fact that CGMs are precautionary devices that are not DME or medically necessary for long-term usage. In this case, though, SecureHorizons included its Diabetic Management, Equipment and Supplies Policy which explains why CGMs are considered precautionary devices that do not qualify as DME. As the policy states, CGMs are only intended to be used on a short-term basis. Because their usage is indicated for a period of no longer than three days, they do not meet the Medicare standards for DME. A.R. 573, 577. Third, the parties to the present litigation do not know the circumstances behind the contractor's or MA organization's decisions not to appeal the unfavorable decisions. Overall, in light of the distinguishing factors and the non-precedential nature of the referenced decisions, Plaintiff's

attempt to show that the Secretary's position was unreasonable or not substantially justified because of two unrelated ALJ decisions should fail.

Plaintiff's reliance on *In Re LCD Complaint of Carol Lewis,* DAB Docket No. C-15-1021, is similarly misplaced. Based on Plaintiff's description of that case, it appears that *In Re LCD Complaint of Carol Lewis* is a challenge to the validity of a LCD under 42 C.F.R. Part 426. The present case differs significantly in that it is a claims appeal, meaning that Plaintiff accepts that LCD L27231 is valid but disputes how it was applied to her request for a CGM. Given that the two cases present two very different issues, Plaintiff cannot legitimately argue that the contractor's actions in *In Re LCD Complaint of Carol Lewis* support the notion that the Secretary acted unreasonably here.

Significantly, there are Council decisions that are consistent with its decision in the present case. For example, *In the case of J.M.*, 2013 WL 7965732, the Council upheld an ALJ's denial of a CGM for a beneficiary who, like Plaintiff, suffered Type 1 diabetes. In denying the request for a CGM, the Council relied upon an article that characterized CGMs as precautionary devices that do not qualify for coverage under Medicare's DME benefit. In support of its holding, the Council explained that the FDA had found that personal CGMs were only to be used to supplement standard self-monitoring of blood glucose levels via fingerstick and that they were not intended to be used more than once every six months. Based on this, the Council held that CGMs are, indeed, precautionary devices that do not qualify for coverage under Medicare's DME benefit.

The Secretary's position in this case is consistent with her position in *In the case of J.M.* In both cases the Secretary denied coverage for a CGM based on policy articles that characterized CGMs as precautionary devices not covered under Medicare's DME benefit.

Further, both cases included evidence explaining that CGMs are not intended to replace self-monitoring of blood glucose levels via fingerstick and that personal CGMs are not intended for long-term use. In other words, the Secretary has long held that CGMs do not fit within the DME benefit category, and as a result, they are not covered under Medicare. In light of the Council's prior decisions, Plaintiff's argument that the Secretary's position is indefensible must fail.[2]

Finally, although this Court found that the Secretary erred in relying on Policy Article A47238, her reliance on that article was reasonable. The Secretary makes coverage determinations using different methods. For example, the Secretary is entitled to make coverage decisions on a case-by-case basis. Alternatively, the Secretary can issue NCDs that set forth national policy regarding coverage of specific items. 42 U.S.C. § 1395ff(f)(1)(b); 42 C.F.R. § 405.1062(a). Coverage decisions can also be made based on LCDs, which apply to certain geographic areas. 42 U.S.C. §1395ff(f)(2)(B). As discussed in the Secretary's brief on the merits, LCDs were created to replace Local Medical Review Policies (LMRP). Unlike LMRPs, LCDs only include reasonable and necessary determinations. Because of this, MACs develop policy articles that include information regarding payment and coding. According to Medicare's Program Integrity Manual, Internet Only Manual 100-08, Chapter 13, Section 13.1.3, policy articles can also include whether a benefit category is met. Although the Secretary understands that Medicare manuals do not have the force and effect of law, they are entitled to deference. *Skidmore v. Swift & Co.*, 323 U.S. 134, 137-140 (1944). Thus, the Secretary reasonably relied upon Policy Article A47238 because, consistent with the information in the Medicare Program Integrity Manual, it included information regarding whether CGMs meet the definition for DME.

[2] The Secretary also denied coverage for personal CGMs in *In the case of J.S.*, 2011 WL 6968051, and *In the case of K.M.*, 2010 WL 4877156.

IV. CONCLUSION

Overall, the Secretary's position throughout the administrative proceedings and before this Court has been substantially justified. As held by this court, the Secretary correctly found that NCD 40.2 and LCD L27231 do not provide coverage for CGMs. While this Court disagreed with the Secretary's reliance on Policy Article A47231 to deny coverage, the Secretary's reliance on it was not unreasonable. Consequently, Plaintiff is not entitled to a fee award pursuant to the EAJA.

Respectfully submitted,

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